



## Press release

# Orexo acquires all US rights for Abstral and receives a net cash consideration of MSEK 610

## Telephone conference today June 4 at 10:00am CET

**Uppsala, Sweden – June 4, 2012** - Orexo AB (“Orexo”) today announced the acquisition of the US rights to Abstral® from ProStrakan Group plc (“ProStrakan”) and the restructure of the existing royalty arrangement for the product in EU and Rest-of-the-World markets (ROW). Completion of the transaction in the US is anticipated by January 1, 2013, while EU and ROW were completed as of June 1, 2012.

### **Orexo receives 610 MSEK**

Fixed payments of 610 MSEK to be received by Orexo as part of the revised agreement, combined with expected future royalties and milestone awards from Abstral sales in ex-US markets, will secure a strong financial position from which to execute future US commercial activities.

### **Orexo prepares for forward integration**

This development is fully in-line with the Company’s strategy, as communicated during the last year, where Orexo itself will seek to commercialize the proprietary products which arise from application of its patented sublingual delivery technology. Abstral was originally developed by Orexo and out-licensed to ProStrakan.

Abstral is a rapid-acting formulation of fentanyl, employing Orexo’s proprietary sublingual delivery technology, which is approved and marketed for the treatment of breakthrough pain in cancer patients in both the US and EU.

With acquisition of the US rights, Orexo has taken an important step towards establishing a commercial presence in the US.

### **Abstral to be Orexo’s first commercial brand in US**

Since 2010, Orexo has committed to establishing a commercial presence in the US through which to launch its proprietary products. In Abstral, Orexo has secured its first US commercial brand as of January 1, 2013.

### **Orexo to have two specialty pharmaceuticals in the US**

The establishment of a commercial presence in the US will now be in advance of the FDA filing of Orexo’s lead value driver; OX219. From early 2014, it is expected that Orexo will be very well positioned in the US market through full ownership of two commercial specialty pharmaceutical brands.

- **Abstral** - the leading, new fast-acting fentanyl product in EU intended for treatment of breakthrough pain in cancer patients. The product is already approved and available in the US.
- **OX219** – sublingual reformulation of buprenorphine and naloxone using Orexo’s technology. The program is developed for maintenance treatment of opioid dependence and may be the first



new entrant in to a rapidly growing US\$1.3 billion market. Orexo expects to file OX219 with the FDA in Q1 2013.

### **Orexo to launch Abstral in the US market as of January 1, 2013**

The new agreement will see the existing commercial infrastructure continue to market Abstral in the US until December 31, 2012 under ProStrakan's direction. In the seven-month period, until Orexo assumes full operational responsibility, a detailed commercial plan will be developed to ensure the establishment of Abstral as the leading, new fast-acting fentanyl product in the US, as has been achieved in EU. Orexo will in Q4 2012 present the commercial plan for Abstral in the US.

Anders Lundström, Chief Executive, of Orexo said:

“Since launch in 2008, Abstral has gained the position as the leading new treatment of breakthrough pain in cancer patients in EU markets. Orexo is confident that the success we have witnessed in EU can be mirrored in the US, through execution of an optimized commercial strategy.”

### **Overall deal value and royalties lay a solid financial foundation for Orexo**

The agreement with ProStrakan is based on a full acquisition of all US rights to Abstral from January 1, 2013 and a net cash consideration of MGBP 55 (approx. MSEK 610), which is to be paid to Orexo in three installments over the coming 24 months (MGBP 22.5 in 2012, MGBP 20.0 in 2013 and MGBP 12.5 in 2014). The consideration is a fixed royalty, which arises from the restructure of existing US and non-US royalty and milestone schedules between Orexo and ProStrakan and will be reported as income over three years starting from June 2012. The sale of Orexo's 50 percent share in the Nordic Joint-venture is also part of the net consideration.

### **Continued royalty and milestone income from Abstral in EU and RoW**

The new agreement also ensures that Orexo will continue to receive future royalty payments from sales of Abstral in the EU and RoW markets. Royalties in EU will start at 15% of annual sales exceeding MEUR 42.5 (approx. MSEK 380) and will increase to 20% on annual sales exceeding MEUR 60 (approx. MSEK 540). Orexo can also expect milestone payments of up to MGBP 10 (approx. MSEK 110), when annual sales exceed certain thresholds in the EU. ProStrakan will pay royalties on sales in EU according to the original agreement up to, and including, May 2012. Following the receipt of these amounts, no additional milestone and royalty payments from EU sales of Abstral are expected in 2012 and 2013.

During 2011 Orexo received MSEK 70.5 in royalties related to Abstral and during the first quarter 2012 the company reported a royalty income from Abstral of MSEK 19.4. A sales milestone of MEUR 3.3 (approx. MSEK 30) was reached and received in May 2012.

In all other territories (RoW), with the exception of Japan where the existing agreement will continue, Orexo will receive a 15% royalty on net sales increasing to 20% when annual sales exceed MEUR 12.5 (approx. MSEK 110). In addition, Orexo will also retain the rights to all further development and sales milestones in the ROW markets.

Martin Nicklasson, Chairman of the Board of Directors at Orexo commented:



“I am very satisfied with the revised Abstral agreement, as it sees Orexo gaining full US-rights to the brand, monetising much of the current value of the existing EU and ROW agreements, while reducing financial risks. Furthermore, with the revised royalty structure Orexo still retains much of the upside associated with increasing EU and ROW sales, which can be expected to contribute to Orexo’s cash flow in the years to come.”

### **Telephone conference**

CEO Anders Lundström will together with Chairman Martin Nicklasson present the background to the agreement with ProStrakan at a teleconference today at 10.00am CET. The audiocast will be accessible live via the link below and on the website.

Internet: <http://livecast.wehay.com/stockontv/120604/orexo/>

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### **About Orexo**

Orexo AB is an emerging specialty pharma company developing improved treatments using proprietary drug delivery technology. Orexo’s expertise is within the area of reformulation technologies and especially sublingual formulations.

Orexo has a portfolio of revenue generating EU and US approved products currently marketed under licence and a pipeline of several reformulations of approved compounds for areas of unmet medical need. Orexo also has collaboration projects with several international pharma companies.

Orexo AB is Swedish headquartered with 100 employees and listed on NASDAQ-OMX. The largest shareholders are Danish Novo A/S and Swedish HealthCap.

### **About Abstral**

Abstral is the novel, rapidly-disintegrating, sublingual (under the tongue) formulation of fentanyl, a well-established opioid used for the management of episodes of breakthrough pain experienced by cancer patients who are already receiving opioid analgesics for chronic pain. Abstral is approved in the EU, US and Canadian markets.

### **About OX219**

OX219 is a sublingual formulation of buprenorphine /naloxone using Orexo’s proprietary technology. OX219 is intended for maintenance treatment of people suffering from opioid-dependence.

Through application of its proprietary technologies Orexo has, increased bioavailability of the active ingredient, accelerated disintegration time, reduced tablet size and improved taste and “mouth feel” compared to the original Suboxone® tablet.



OX219 has the potential to be the 1st new entrant into a US\$1.3bn market, with more than 2.3 million patients suffering from opioid dependence and majority of patients are not adequately treated today. OX219 is expected to be filed with the FDA in Q1 2013.

For information about Orexo please visit [www.orexo.com](http://www.orexo.com)

*Note: This is information that Orexo AB (publ) discloses pursuant to the Financial Instruments Trading Act and/or Securities Market Act. The information was provided for public release on June 4, 2012 at 08:05 CET. This press release has been prepared in both Swedish and English. In the event of any discrepancy in the content of the two versions, the Swedish version shall take*